

Exhibit 2

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

NIVAGEN, INC.,

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.

Defendant.

Case No.: 2:24-cv-36-RWS-RSP

**REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE
(LETTERS ROGATORY)**

TO THE APPROPRIATE JUDICIAL AUTHORITY OF JAPAN:

The United States District Court for the Eastern District of Texas presents its compliments to the appropriate Judicial Authority of Japan and requests international judicial assistance to obtain evidence to be used in a civil proceeding before this Court in the above-captioned matter. A trial on this matter is scheduled for approximately February 17, 2026, in Marshall, Texas, United States of America.

This Court, the United States District Court for the Eastern District of Texas, Marshall Division, has jurisdiction over this proceeding. In the proper exercise of its authority, this Court has determined that the evidence cannot be secured except by the intervention of Japan's judicial authorities.

This Court requests assistance in serving the interests of justice. The assistance requested is that the appropriate Judicial Authorities of Japan cause:

Nobelpharma Co., Ltd.
NMF Kayabacho Building
1-17-24, Shinkawa, Chuo-ku

Tokyo 104-0033, Japan
Telephone: +81-3-6670-3800
Facsimile: +81-3-6670-3801

to provide testimony and produce documents as provided below.

1. (a) Nature of the proceeding

The nature of the proceedings is a patent infringement lawsuit commenced by Nivagen, Inc. (“Plaintiff”) against Sun Pharmaceutical Industries, Inc. (“Sun”) in the United States District Court for the Eastern District of Texas. Plaintiff alleges that Sun has infringed U.S. Patent Nos. 11,406,598 (“the ’598 patent”) and 11,878,076 (“the ’076 patent”) (collectively, “Asserted Patents”) under 35 U.S.C. § 271(b)-(c). The subject matter of the Asserted Patents relates to a pharmaceutical lyophilized phenobarbital sodium injection and methods of manufacturing phenobarbital sodium injections involving lyophilization. Phenobarbital sodium is a drug commonly used in the treatment of neonatal seizures.

Plaintiff alleges that Sun has infringed the Asserted Patents by manufacturing, offering for sale, and selling Sun’s phenobarbital sodium drug product “Sezaby” which was approved by the United States Food and Drug Administration on November 17, 2022. Sun denies that Plaintiff’s claims have merit and asserts that the Asserted Patents are invalid, and that Sun does not infringe them.

(b) Summary of the Complaint

Plaintiff alleges that it is the owner of all rights, title, and interest in the Asserted Patents. Plaintiff alleges that Sun makes, uses, offers for sale, sells, and/or imports product in the United States that would infringe one or more claims of the Asserted Patents. Plaintiff seeks judgment against Sun for infringement of the Asserted Patents and requests that the court award damages to Plaintiff in an amount to be proven at trial.

(c) Summary of the defenses

Sun denies that it has infringed the Asserted Patents and claims that the Asserted Patents are invalid. Sun advances invalidity arguments under U.S. 35 U.S.C. §§ 102 and/or 103, citing prior art (prior published work) that renders the claims obvious or anticipated by one of ordinary skill and training in the art, and for lack of enablement, written description, or indefiniteness.

2. (a) Evidence to be obtained

This Court requests that the Judicial Authority of Japan cause the appropriate order to be issued to compel the production of certain relevant documents in the custody and possession of Nobelpharma Co., Ltd. (“Nobelpharma”), and to compel the testimony of a Nobelpharma representative. Specifically, this Court requests that the Judicial Authority order Nobelpharma to produce the documents set forth below (“Document Requests”) and compel testimony responsive to the questions set forth below (“Witness Questions”).

(b) Purpose of the evidence sought

Sun has represented to the Court that the documentary evidence sought is material to its defense, because it will show that the Asserted Patents are invalid based on prior published art. The Court has determined, based on the parties’ submissions, that Nobelpharma, the Japanese entity from which Sun seeks discovery, is likely to possess the documents and information sought. In particular, Nobelpharma manufactures, markets, and sells its lyophilized phenobarbital sodium drug product NOBELBAR[®], which was approved in Japan and launched on December 16, 2008. Certain inherent properties of NOBELBAR[®] are not explicitly disclosed in the public domain (for example, whether it is amorphous, or the levels of certain impurities).

As part of Nobelpharma’s involvement in the drug approval process through the Pharmaceuticals and Medical Devices Agency (“PMDA”) and the Ministry of Health, Labour, and Welfare (“MHLW”), Nobelpharma submitted a New Drug Application for NOBELBAR[®] that included records and technical documents detailing important pharmaceutical elements, such as the manufacturing process, stability, impurities, and other drug characteristics of NOBELBAR[®]. Since these documents and records existed before the filing of the Asserted Patents, they serve as prior art, rendering them directly relevant to Sun’s invalidity defenses.

3. Documents to be Produced

- a. The technical documents that demonstrate the manufacturing process of NOBELBAR[®] for intravenous injection as used prior to September 20, 2019, including, but not limited to, the list of excipients or carriers, the process of lyophilization and lyophilization parameters.

- b. The documents submitted with the New Drug Application that evidence the stability testing of NOBELBAR[®] for intravenous injection over time (e.g., over NOBELBAR[®]'s shelf life), prior to September 20, 2019.
- c. The documents submitted with the New Drug Application that evidence the impurities and degradants present in NOBELBAR[®] for intravenous injection, including the content and qualification specifically of 2-ethyl-2-phenylmalonamide (2EPMM), alpha-phenylbutyrylguanidine (PBG), and/or phenylethylacetylurea (PEAU), prior to September 20, 2019.
- d. The documents submitted with the New Drug Application that evidence the structural characterization of phenobarbital sodium active pharmaceutical ingredient (API) and the final drug product of NOBELBAR[®] for intravenous injection prior to September 20, 2019, including specifically whether the API is amorphous (e.g., x-ray diffraction diffractograms).
- e. The documents submitted with the New Drug Application that evidence the purity of NOBELBAR[®] for intravenous injection, including assays and moisture content of phenobarbital sodium active pharmaceutical ingredient prior to September 20, 2019.

4. (a) Person to be examined

In the United States, under Federal Rule of Civil Procedure 30(b)(6), a party may require a corporation to designate a representative to provide testimony on its behalf concerning specific topics relevant to a case. The designated individual must testify about information known or reasonably available to the corporation. This mechanism ensures that the entity provides accurate and comprehensive testimony on relevant matters.

The Court respectfully requests that the Judicial Authority of Japan similarly compel Nobelpharma to designate a representative to provide testimony on the Witness Questions.

It is requested that the examination of the witness be conducted under oath or affirmation. No particular form is requested. If the evidence cannot be taken in the manner requested, it is requested that the evidence be taken in such a manner as provided by local law for the formal taking of evidence.

(b) Witness Questions

This Court respectfully requests the appropriate Judicial Authority to ask the designated Nobelpharma representative the following questions:

- a. Describe the results of any long-term or accelerated stability studies performed on NOBELBAR® as documented in its New Drug Application.
- b. Identify what tests were conducted to assess the purity of NOBELBAR® prior to September 20, 2019.
- c. Describe the impurity profile of NOBELBAR® as documented in the New Drug Application and the amounts, if any, of 2-ethyl-2-phenylmalonamide (2EPMM), alpha-phenylbutyrylguanidine (PBG), and/or phenylethylacetylurea (PEAU) over time, prior to September 20, 2019.
- d. Explain the structural characterization of the phenobarbital sodium active pharmaceutical ingredient (API) in NOBELBAR® submitted with the New Drug Application, e.g., is it amorphous.
- e. Explain the structural characterization of NOBELBAR® submitted with the New Drug Application.
- f. Were any studies conducted to determine whether NOBELBAR® was amorphous prior to September 20, 2019? If so, describe the results (e.g., was the composition amorphous?).
- g. Do you have personal knowledge of the process by which the documents produced were created, maintained, or stored?
- h. Are you a custodian of records or a person qualified to testify regarding the record-keeping practices of Nobelpharma?
- i. Were the documents produced or relied upon by Nobelpharma created in the regular course of business at or near the time of the events they record?
- j. Was it a regular practice of Nobelpharma to create these type of documents as a part of its routine operations?
- k. Are the documents produced true and correct copies of the original records that are regularly kept by Nobelpharma?

5. Special methods or procedures requested

First, this Court respectfully requests that the Judicial Authority provide a verbatim transcript of the testimony given. This transcript is essential for an accurate record of the witness's statements to be used in the ongoing proceedings. Please note that Sun will be fully responsible for any costs or reimbursements incurred as a result of preparing and delivering this transcript, including providing a stenographer if required.

Second, the evidence provided in response to this Letter may include confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than in the above-captioned matter may be warranted. This Court has entered a protective order in this case, which allows for the production of documents by parties or by third parties to be subject to protections against the disclosure of confidential documents, or the information they contain, and for the protection of testimony designated as confidential from disclosure. The protective order is attached as **Attachment A**. Under the protective order, Nobelpharma may designate documents as confidential, and the Court will apply the protective order with respect to Nobelpharma's documents just as it would to documents produced by US parties.

In addition, the requests for documents are not intended to seek documents protected by attorney-client privilege or attorney work product protections. Under U.S. law, attorney-client privilege protects confidential communications between a client and their attorney made for the purpose of seeking or providing legal advice. Similarly, the work product doctrine shields materials prepared by or for an attorney in anticipation of litigation, safeguarding legal strategies, mental impression, and other attorney-created content. Consequently, any materials falling under these protections should not be produced in response to this request.

Third, because this letter seeks evidence for admission at trial, and because the US law of evidence requires that evidence must be authenticated before it can be admitted at trial and requires evidence of certain facts before business records containing hearsay can be admitted at trial, the Court requests that the Judicial Authority require Nobelpharma, by an appropriate corporate representative, execute the declaration attached to this letter as **Attachment B**, which is in a form ordinarily used in the United States to authenticate business records for use at trial without the

need for a witness to testify concerning the documents. The declaration is drafted to meet the requirements of Rule 803(6) of the Federal Rules of Evidence, which defines the business records exception to the hearsay rule, and Rule 902(12) of the Federal Rules of Evidence, which defines the requirements for a declaration that can serve to authenticate foreign business records. In order to meet the requirements of Rule 902(12), the Court respectfully requests that the declaration be executed in a manner that would, if false, subject the maker to a criminal penalty under Japanese law (for example, an affidavit sworn before a notary). If that written certification is completed, then the appropriate Judicial Authority of Japan need not put questions g through k to the witness.

Finally, this Court respectfully requests that a complete copy of all documents produced, as well as the transcript of the testimony taken, be sent to Sun's counsel. This will ensure that the necessary evidence is properly reviewed and evaluated in preparation for use at trial. Please send the copies directly to Sun's counsel at the address provided:

Samuel T. Lockner
Carlson, Caspers, Vandenburg & Linquist, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402
+1-612-436-9600
slockner@carlsoncaspers.com
sun-sezaby@carlsoncaspers.com

6. Request for notification of time and place

A response is requested by February 1, 2025, or as soon as practicable. Expedient treatment of this request will allow the parties to obtain and review the produced documents and obtain testimony before August 8, 2025, by which date, under the current schedule, the parties are to have completed the process of obtaining evidence in preparation for trial.

7. Reciprocity

Pursuant to 28 U.S.C. § 1782, this Court is willing to provide similar assistance to the Judicial Authorities of Japan.

8. Reimbursement of Costs

Any reimbursable costs due to the appropriate Judicial Authority of Japan will be reimbursed by the attorneys for Sun. Please direct any correspondence or communication concerning costs to:

Samuel T. Lockner
Carlson, Caspers, Vandenburg & Linquist, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402
+1-612-436-9600
slockner@carlsoncaspers.com
sun-sezaby@carlsoncaspers.com

The Court will compel the reimbursement of costs upon request from the appropriate Judicial Authority of Japan.

WITNESS my hand and seal of said Court in the Eastern District of Texas, on this ____
day of _____, 2024.

IT IS SO ORDERED

ROBERT W. SCHROEDER III
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Attachment A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

NIVAGEN, INC.

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC..

Defendant.

Case No.: 2:24-cv-00036-RWS-RSP

PROTECTIVE ORDER

WHEREAS, Plaintiff Nivagen and Defendant Sun Pharmaceuticals Industries, Inc., hereafter referred to as " the Parties," believe that certain information that is or will be encompassed by discovery demands by the Parties involves the production or disclosure of trade secrets, confidential business information, or other proprietary information;

WHEREAS, the Parties seek a protective order limiting disclosure thereof in accordance with Federal Rule of Civil Procedure 26(c):

THEREFORE, it is hereby stipulated among the Parties and ORDERED that:

1. Each Party may designate as confidential for protection under this Order, in whole or in part, any document, information or material that constitutes or includes, in whole or in part, confidential or proprietary information or trade secrets of the Party or a Third Party to whom the Party reasonably believes it owes an obligation of confidentiality with respect to such document, information or material ("Protected Material"). Protected Material shall be designated by the Party producing it by affixing a legend or stamp on such document,

information or material as follows: “CONFIDENTIAL.” The word “CONFIDENTIAL” shall be placed clearly on each page of the Protected Material (except deposition and hearing transcripts) for which such protection is sought. For deposition and hearing transcripts, the word “CONFIDENTIAL” shall be placed on the cover page of the transcript (if not already present on the cover page of the transcript when received from the court reporter) by each attorney receiving a copy of the transcript after that attorney receives notice of the designation of some or all of that transcript as “CONFIDENTIAL.” Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the producing Party and a unique identifying number. Likewise, each discrete unit of tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the producing Party and a unique identifying number.

2. Any document produced under Patent Rules 2-2, 3-2, and/or 3-4 before issuance of this Order with the designation “Confidential” or “Confidential - Outside Attorneys’ Eyes Only” shall receive the same treatment as if designated “RESTRICTED - ATTORNEYS’ EYES ONLY” under this Order, unless and until such document is redesignated to have a different classification under this Order.
3. With respect to documents, information or material designated “CONFIDENTIAL,” or “RESTRICTED - ATTORNEYS’ EYES ONLY,”¹ subject to the provisions herein and unless otherwise stated, this Order governs, without limitation: (a) all documents, electronically stored information, and/or things as defined by the Federal Rules of Civil Procedure; (b) all pretrial, hearing or deposition testimony, or documents marked as exhibits

¹ The term DESIGNATED MATERIAL is used throughout this Protective Order to refer to the class of materials designated as “CONFIDENTIAL,” or “RESTRICTED - ATTORNEYS’ EYES ONLY,” both individually and collectively.

or for identification in depositions and hearings; (c) pretrial pleadings, exhibits to pleadings and other court filings; (d) affidavits; and (e) stipulations. All copies, reproductions, extracts, digests and complete or partial summaries prepared from any DESIGNATED MATERIALS shall also be considered DESIGNATED MATERIAL and treated as such under this Order.

4. A designation of Protected Material (i.e., “CONFIDENTIAL,” or “RESTRICTED - ATTORNEYS’ EYES ONLY”) may be made at any time. Inadvertent or unintentional production of documents, information or material that has not been designated as DESIGNATED MATERIAL shall not be deemed a waiver in whole or in part of a claim for confidential treatment. Any party that inadvertently or unintentionally produces Protected Material without designating it as DESIGNATED MATERIAL may request destruction of that Protected Material by notifying the recipient(s), as soon as reasonably possible after the producing Party becomes aware of the inadvertent or unintentional disclosure, and providing replacement Protected Material that is properly designated. The recipient(s) shall then destroy all copies of the inadvertently or unintentionally produced Protected Materials and any documents, information or material derived from or based thereon.
5. “CONFIDENTIAL” documents, information and material may be disclosed only to the following persons, except upon receipt of the prior written consent of the designating party, upon order of the Court, or as set forth in paragraph 13 herein:
 - (a) outside counsel of record in this Action for the Parties;
 - (b) employees of such counsel assigned to and reasonably necessary to assist such counsel in the litigation of this Action;
 - (c) in-house counsel for the Parties who either have responsibility for making decisions dealing directly with the litigation of this Action, or who are assisting outside counsel in the litigation of this Action;

- (d) up to and including three (3) designated representatives of each of the Parties to the extent reasonably necessary for the litigation of this Action, except that either party may in good faith request the other party's consent to designate one or more additional representatives, the other party shall not unreasonably withhold such consent, and the requesting party may seek leave of Court to designate such additional representative(s) if the requesting party believes the other party has unreasonably withheld such consent;
 - (e) outside consultants or experts (*i.e.*, not existing employees or affiliates of a Party or an affiliate of a Party) retained for the purpose of this litigation, provided that: (1) such consultants or experts are not presently employed by the Parties hereto for purposes other than this Action²; (2) before access is given, the consultant or expert has completed the Undertaking attached as Exhibit A hereto and the same is served upon the producing Party with a current curriculum vitae of the consultant or expert at least ten (10) days before access to the Protected Material is to be given to that consultant or Undertaking to object to and notify the receiving Party in writing that it objects to disclosure of Protected Material to the consultant or expert. The Parties agree to promptly confer and use good faith to resolve any such objection. If the Parties are unable to resolve any objection, the objecting Party may file a motion with the Court within fifteen (15) days of the notice, or within such other time as the Parties may agree, seeking a protective order with respect to the proposed disclosure. The objecting Party shall have the burden of proving the need for a protective order. No disclosure shall occur until all such objections are resolved by agreement or Court order;
 - (f) independent litigation support services, including persons working for or as court reporters, graphics or design services, jury or trial consulting services, and photocopy, document imaging, and database services retained by counsel and reasonably necessary to assist counsel with the litigation of this Action; and
 - (g) the Court and its personnel.
6. A Party shall designate documents, information or material as "CONFIDENTIAL" only upon a good faith belief that the documents, information or material contains confidential or proprietary information or trade secrets of the Party or a Third Party to whom the Party reasonably believes it owes an obligation of confidentiality with respect to such documents,

² For clarity, nothing herein shall prevent a party from using an expert retained for this Action in connection with a post grant review or *inter partes* review proceeding relating to one or both of the patents-in-suit provided that the expert adheres to the requirements set forth herein.

information or material.

7. Documents, information or material produced pursuant to any discovery request in this Action, including but not limited to Protected Material designated as DESIGNATED MATERIAL, shall be used by the Parties only in the litigation of this Action and shall not be used for any other purpose; provided, however, that Defendant may use Plaintiff's DESIGNATED MATERIAL in connection with post grant review or *inter partes* review proceedings relating to one or both of the patents-in-suit so long as Defendant adheres to the terms of this protective order and any protective order filed in connection with any such post grant review or *inter partes* review proceedings.³ Any person or entity who obtains access to DESIGNATED MATERIAL or the contents thereof pursuant to this Order shall not make any copies, duplicates, extracts, summaries or descriptions of such DESIGNATED MATERIAL or any portion thereof except as may be reasonably necessary in the litigation of this Action (or a post grant review or *inter partes* review proceeding directed to one or both of the patents-in-suit). Any such copies, duplicates, extracts, summaries or descriptions shall be classified DESIGNATED MATERIALS and subject to all of the terms and conditions of this Order.
8. Any individual listed in Paragraph 5(a-e) who has accessed or reviewed DESIGNATED MATERIAL (materials designated as "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY") shall not participate in or aid in, directly or indirectly, the preparation or filing of any FDA Citizen Petition related to compounds, compositions,

³ For clarity, Defendant shall comply with the terms of this protective order with respect to any Designated Material used in this Action and shall comply with terms of the protective order entered in connection with a post grant review or *inter partes* review relating to one or both of the patents-in-suit with respect to any Designated Material used in any such proceeding.

formulations, or products containing phenobarbital or phenobarbital sodium for one (1) year after the termination of this Action, including any appeals. However, this shall not preclude involvement in responding to any FDA Citizen Petition related to pharmaceutical compounds, compositions, formulations, or products containing phenobarbital or phenobarbital sodium filed by a third party to this Action with respect such Party's own product.

9. To the extent a producing Party believes that certain Protected Material qualifying to be designated CONFIDENTIAL is so sensitive that its dissemination deserves even further limitation, the producing Party may designate such Protected Material "RESTRICTED -- ATTORNEYS' EYES ONLY."
10. For Protected Material designated RESTRICTED -- ATTORNEYS' EYES ONLY, access to, and disclosure of, such Protected Material shall be limited to individuals listed in paragraphs 5(a-c) and (e-g); provided, however, that access by in-house counsel pursuant to paragraph 5(c) be limited to in-house counsel who exercise no competitive decision-making authority on behalf of the client and who is bound by paragraph 11.
11. Any attorney representing a Party, whether in-house or outside counsel, and any person associated with a Party and permitted to receive the other Party's DESIGNATED MATERIAL (materials designated as "CONFIDENTIAL," or "RESTRICTED - ATTORNEYS' EYES ONLY"), who obtains, receives, has access to, or otherwise learns, in whole or in part, the other Party's DESIGNATED MATERIAL under this Order shall not directly or indirectly prepare, prosecute, supervise, or assist in the preparation or prosecution of any patent application pertaining to the field of the invention of the patents-in-suit on behalf of the receiving Party or its acquirer, successor, predecessor, or other

affiliate during the pendency of this Action and for two years after its conclusion, including any appeals. To ensure compliance with the purpose of this provision, each Party shall create an “Ethical Wall” between those persons with access to DESIGNATED MATERIAL and any individuals who, on behalf of the Party or its acquirer, successor, predecessor, or other affiliate, prepare, prosecute, supervise or assist in the preparation or prosecution of any patent application pertaining to the field of invention of the patent-in-suit. Notwithstanding the foregoing, nothing herein shall preclude individuals listed in Paragraph 5(a-e) from working on and participating in, directly or indirectly, (i) all aspects of any *inter partes* review, post-grant review, or re-issue or re-examination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board concerning the patents-in-suit, except for claim drafting, and (ii) all aspects of any pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court for a patent or patent application except for claim drafting. To avoid any misunderstanding, and consistent with the scope of the foregoing terms, nothing herein shall preclude the individuals listed in Paragraph 5(a-e) from engaging in supervisory roles in patent prosecution concerning the field of the invention of the patents-in-suit that do not involve drafting, amending, or providing instruction with respect to the drafting or amending of claims, or being involved in proceedings or litigations relating to patent term extension under 35 U.S.C. § 156 *et seq.* or patent term adjustment under 35 U.S.C. § 154 *et seq.* for a patent or patent application concerning the field of the invention of the patents-in-suit.

12. Nothing in this Order shall prejudice the right of any party to oppose production of any information for lack of relevance. Nonetheless, information in a document may be redacted on the basis of relevance only to the extent such information concerns another product that

is not at issue in this Action. Redactions on this basis shall identify where such information was redacted and shall include a “Prod” or “Product” label.

13. Nothing in this Order shall require production of documents, information or other material that a Party contends is protected from disclosure by the attorney-client privilege, the work product doctrine, or other privilege, doctrine, or immunity. If documents, information or other material subject to a claim of attorney-client privilege, work product doctrine, or other privilege, doctrine, or immunity is inadvertently or unintentionally produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any such privilege, doctrine, or immunity. Any Party that inadvertently or unintentionally produces documents, information or other material it reasonably believes are protected under the attorney-client privilege, work product doctrine, or other privilege, doctrine, or immunity may obtain the return of such documents, information or other material by promptly notifying the recipient(s) and providing a privilege log for the inadvertently or unintentionally produced documents, information or other material. The recipient(s) shall gather and return all copies of such documents, information or other material to the producing Party, except for any pages containing privileged or otherwise protected markings by the recipient(s), which pages shall instead be destroyed and certified as such to the producing Party.
14. There shall be no disclosure of any DESIGNATED MATERIAL by any person authorized to have access thereto to any person who is not authorized for such access under this Order. The Parties are hereby ORDERED to safeguard all such documents, information and material to protect against disclosure to any unauthorized persons or entities.
15. Nothing contained herein shall be construed to prejudice any Party’s right to use any

DESIGNATED MATERIAL in taking testimony at any deposition or hearing provided that the DESIGNATED MATERIAL is only disclosed to a person(s) who is: (i) eligible to have access to the DESIGNATED MATERIAL by virtue of his or her employment with the designating party, (ii) identified in the DESIGNATED MATERIAL as an author, addressee, or copy recipient of such information, (iii) although not identified as an author, addressee, or copy recipient of such DESIGNATED MATERIAL, has, in the ordinary course of business, seen such DESIGNATED MATERIAL, (iv) a current or former officer, director or employee of the producing Party or a current or former officer, director or employee of a company affiliated with the producing Party; (v) counsel for a Party, including outside counsel and in-house counsel (subject to paragraph 10 of this Order); (vi) an independent contractor, consultant, and/or expert retained for the purpose of this litigation; (vii) court reporters and videographers; (viii) the Court; or (ix) other persons entitled hereunder to access to DESIGNATED MATERIAL. DESIGNATED MATERIAL shall not be disclosed to any other persons unless prior authorization is obtained from counsel representing the producing Party or from the Court.

16. Parties may, at the deposition or hearing or within thirty (30) days after receipt of a deposition or hearing transcript, designate the deposition or hearing transcript or any portion thereof as “CONFIDENTIAL” or “RESTRICTED - ATTORNEY’ EYES ONLY” pursuant to this Order. Access to the deposition or hearing transcript so designated shall be limited in accordance with the terms of this Order. Until expiration of the 30-day period, the entire deposition or hearing transcript shall be treated as “RESTRICTED - ATTORNEY’ EYES ONLY”.
17. Any DESIGNATED MATERIAL that is filed with the Court shall be filed under seal and

shall remain under seal until further order of the Court. The filing party shall be responsible for informing the Clerk of the Court that the filing should be sealed and for placing the legend “FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER” above the caption and conspicuously on each page of the filing. Exhibits to a filing shall conform to the labeling requirements set forth in this Order. If a pretrial pleading filed with the Court, or an exhibit thereto, discloses or relies on confidential documents, information or material, such confidential portions shall be redacted to the extent necessary and the pleading or exhibit filed publicly with the Court.

18. The Order applies to pretrial discovery. Nothing in this Order shall be deemed to prevent the Parties from introducing any DESIGNATED MATERIAL into evidence at the trial of this Action, or from using any information contained in DESIGNATED MATERIAL at the trial of this Action, subject to any pretrial order issued by this Court.
19. A Party may request in writing to the other Party that the designation given to any DESIGNATED MATERIAL be modified or withdrawn. If the designating Party does not agree to redesignation within ten (10) days of receipt of the written request, the requesting Party may apply to the Court for relief. Upon any such application to the Court, the burden shall be on the designating Party to show why its classification is proper. Such application shall be treated procedurally as a motion to compel pursuant to Federal Rules of Civil Procedure 37, subject to the Rule’s provisions relating to sanctions. In making such application, the requirements of the Federal Rules of Civil Procedure and the Local Rules of the Court shall be met. Pending the Court’s determination of the application, the designation of the designating Party shall be maintained.
20. Each outside consultant or expert to whom DESIGNATED MATERIAL is disclosed in

accordance with the terms of this Order shall be advised by counsel of the terms of this Order, shall be informed that he or she is subject to the terms and conditions of this Order, and shall sign an acknowledgment that he or she has received a copy of, has read, and has agreed to be bound by this Order. A copy of the acknowledgment form is attached as Appendix A. Discovery of communications between counsel and any outside consultant or expert retained or specially employed by that counsel shall be limited to factual information, analyses, documents, and data relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all other communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

21. To the extent that any discovery is taken of persons who are not Parties to this Action (“Third Parties”) and in the event that such Third Parties contended the discovery sought involves trade secrets, confidential business information, or other proprietary information, then such Third Parties may agree to be bound by this Order.
22. To the extent that discovery or testimony is taken of Third Parties, the Third Parties may designate as “CONFIDENTIAL” or “RESTRICTED -- ATTORNEYS’ EYES ONLY” any documents, information or other material, in whole or in part, produced or given by such Third Parties. The Third Parties shall have ten (10) days after production of such documents, information or other materials to make such a designation. Until that time period lapses or until such a designation has been made, whichever occurs sooner, all documents, information or other material so produced or given shall be treated as

“CONFIDENTIAL” in accordance with this Order.

23. If any third party requests the production of any DESIGNATED MATERIAL, including, but not limited to, a request by subpoena, the receiving Party in possession of such DESIGNATED MATERIAL must (a) notify the producing Party within seven (7) business days of receiving the request; and (b) permit the producing Party a reasonable opportunity to intervene and be heard.
24. Within thirty (30) days of final termination of this Action, including any appeals, all DESIGNATED MATERIAL, including all copies, duplicates, abstracts, indexes, summaries, descriptions, and excerpts or extracts thereof (excluding excerpts or extracts incorporated into any privileged memoranda of the Parties and materials which have been admitted into evidence in this Action), shall at the producing Party’s election either be returned to the producing Party or be destroyed. The receiving Party shall verify the return or destruction by affidavit furnished to the producing Party, upon the producing Party’s request.
25. The failure to designate documents, information or material in accordance with this Order and the failure to object to a designation at a given time shall not preclude the filing of a motion at a later date seeking to impose such designation or challenging the propriety thereof. The entry of this Order and/or the production of documents, information and material hereunder shall in no way constitute a waiver of any objection to the furnishing thereof, all such objections being hereby preserved.
26. Any Party knowing or believing that any other party is in violation of or intends to violate this Order and has raised the question of violation or potential violation with the opposing party and has been unable to resolve the matter by agreement may move the Court for such relief as may be appropriate in the circumstances. Pending disposition of the motion by the

Court, the Party alleged to be in violation of or intending to violate this Order shall discontinue the performance of and/or shall not undertake the further performance of any action alleged to constitute a violation of this Order.

27. Production of DESIGNATED MATERIAL by each of the Parties shall not be deemed a publication of the documents, information and material (or the contents thereof) produced so as to void or make voidable whatever claim the Parties may have as to the proprietary and confidential nature of the documents, information or other material or its contents.
28. Nothing in this Order shall be construed to effect an abrogation, waiver or limitation of any kind on the rights of each of the Parties to assert any applicable discovery or trial privilege. Notwithstanding the foregoing provisions, this Order shall be without prejudice to the right of any party to challenge the propriety of discovery on grounds of privilege, relevance, and/or materiality, and nothing contained herein shall be construed as a waiver of any objection that might be raised as to the admissibility at trial of any evidentiary material. This Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms.
29. Each of the Parties shall also retain the right to file a motion with the Court (a) to modify this Order to allow disclosure of DESIGNATED MATERIAL to additional persons or entities if reasonably necessary to prepare and present this Action and (b) to apply for additional protection of DESIGNATED MATERIAL.

SIGNED this 2nd day of October, 2024.


ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

NIVAGEN, INC.,

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC., SUN PHARMACEUTICAL INDUSTRIES
LTD., SUN PHARMA ADVANCED RESEARCH
COMPANY LTD., SUN PHARMACEUTICAL
MEDICARE LTD.,

Defendants.

Case No.: 2:24-cv-00036-RWS-RSP

**APPENDIX A
UNDERTAKING OF EXPERTS OR CONSULTANTS REGARDING
PROTECTIVE ORDER**

I, _____, declare that:

1. My address is _____
My current employer is _____
My current occupation is _____
2. I have received a copy of the Protective Order in this action. I have carefully read and understand the provisions of the Protective Order.
3. I will comply with all of the provisions of the Protective Order. I will hold in confidence, will not disclose to anyone not qualified under the Protective Order, and will use only for purposes detailed in Paragraph 7 of the Protective Order any information designated as
"CONFIDENTIAL," or "RESTRICTED -- ATTORNEYS' EYES ONLY" that is disclosed to me.
4. Promptly upon termination of these actions, I will return all documents and things

designated as “CONFIDENTIAL,” or “RESTRICTED -- ATTORNEYS’ EYES ONLY” that came into my possession, and all documents and things that I have prepared relating thereto, to the outside counsel for the party by whom I am employed as detailed in Paragraph 24 of the Protective Order.

5. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this action.

I declare under penalty of perjury that the foregoing is true and correct.

Signature _____

Date _____

ATTACHMENT B

CERTIFICATE OF AUTHENTICITY OF BUSINESS RECORDS

I, the undersigned, _____ with the understanding that I am
Name
subject to criminal penalty under the laws of Japan for an intentionally false declaration, declare
that I am employed as _____ with Nobelpharma, and by reason
Position
of my position am authorized and qualified to make this declaration.

I further declare that to the best of my knowledge and belief the documents provided to
the judicial authority for onwards transmission to the United States District Court for the Eastern
District of Texas, pursuant to the letter of request served on said judicial authority, are original
records or true copies of records which:

1. Were made at or near the time of the occurrence of the matters set forth therein, by (or
from information transmitted by) a person with knowledge of those matters;
2. Were kept in the course of a regularly conducted business activity;
3. Were made by the said business activity as a regular practice; and
4. If not original records, are duplicates of original records.

The original or duplicates of these records were/are maintained in _____.
Location

Date of execution

Signature

Place of execution

Witnessed